REMARKS

In the Office Action dated August 25, 2005, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following three separate and distinct Groups:

I. Claims 1-4 and 13, drawn to modified chicken cystatin proteins, classified in class 530, subclass 350.

II. Claims 5-12, drawn to DNA encoding modified chicken cystatin proteins, classified in class 536, subclass 23.1.

III. Claims 14-16, drawn to methods of using modified chicken cystatin proteins, classified in class 424, subclass 184.1.

The Examiner alleges that Group I is directed to proteins and that Group II is drawn to DNA molecule. The Examiner asserts that Groups I and II are distinct since they are products with a different structure and biological properties. The Examiner's restriction is also based on the ground that methods known in the art used to make the polypeptide require different reagents and parameters from the methods of making the nucleic acid encoding the protein and the method of making the polypeptide does not require the nucleic acid.

The Examiner acknowledges that Groups I and III are related as product and process of use. However, the Examiner contends that in the instant case the method of inhibiting the thermal degradation of surimi can be accomplished via the modified protein of Claim 1, and alternatively, may be accomplished via unmodified chicken cystatin as described on page 1 of the specification. Thus, the Examiner alleges that Group I and Group III represent distinct inventions.

In addition, the Examiner requires the alleged restriction on the ground that Groups I-III have separate classifications.

In order to be fully responsive to the Examiner's requirement for restriction, Applicant provisionally elects to prosecute the subject matter of Group I, claims 1-4 and 13, drawn to modified chicken cystatin proteins, classified in class 530, subclass 350. Applicant reserves the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicant hereby traverses the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

In the outset, Applicant observes that Claims 11-12 are directed to a method for producing modified chicken cystatin proteins of Claim 1. Thus, Applicant respectfully submits that the Examiner erred in stating that Claims 11-12 are directed to DNA molecules. Applicants respectfully submit that Claims 11-12 should be regrouped and considered together with Claims 1-4 and 13.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more <u>independent and distinct</u> inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent <u>and</u> distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

Applicant respectfully submits that Group I and Group II are related since the nucleic acid molecules of Group II encode, and can be used to produce, the modified chicken cystatin protein or composition of Group I. Applicant also submits that Claims 11-12, which Applicant believes that the Examiner mistakenly grouped with Claims 5-10, employ the concept of Group I. Thus, Groups I and II are different aspects of a single invention not independent.

While acknowledging Groups I and III are related as product and process of use, the Examiner has also alleged that Groups I and III are distinct. Applicant submits that the purpose of the method of Group III is to inhibit the thermal degradation of surimi by using the proteins of Group I. Clearly, Group III employs the concept of Group I. Thus, Groups I and III are different aspects of a single invention and not independent.

Applicant respectfully submits that Groups I-III are all different aspects of a single invention. The methods of Claims 11-12 and Group III merely teach how to make and use the proteins of Group I which are encoded by the nucleic acid molecules of Group II.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

The Examiner also states that the inventions have acquired a separate status in the art as evidenced by the separate classification and recognized divergent subject matter and would require independent searches. Thus, the Examiner concludes that restriction for examination purposes is proper.

Reliance on the supposed classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of classes and subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the classes or subclass(es) with which he associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to

different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

Applicant respectfully suggests that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is

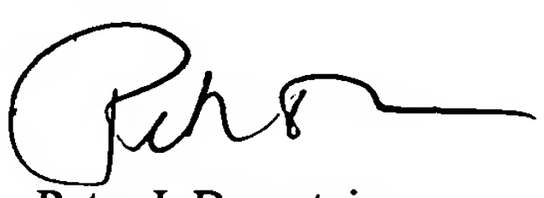
available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicant respectfully urges the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicant respectfully submits that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined three groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims. Alternatively, Applicant respectfully submits that the Examiner should at least consider Claims 11-12 together with Group I.

Respectfully submitted,



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